

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,)	
<u>ex rel.</u> PAUL CAIRNS, et al.,)	
)	
Plaintiff,)	
)	
v.)	No. 1:12 CV 00004 AGF
)	
D.S. MEDICAL, L.L.C., et al.,)	
)	
Defendants.)	

PLAINTIFF'S PRE-TRIAL BRIEF

Plaintiff, the United States of America, respectfully submits its pre-trial brief.

I. Background

At trial, the United States will seek to prove three counts under the False Claims Act (FCA), 31 U.S.C. §§ 3729-33, against four Defendants: Dr. Sonjay Fonn, a neurosurgeon; his limited liability company, Midwest Neurosurgeons, LLC (Midwest Neurosurgeons); his fiancée, Ms. Deborah Seeger; and her spinal implant distributorship, DS Medical, LLC (DS Medical). These three FCA counts are predicated on violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (AKS). Counts I and II allege that the Defendants violated 31 U.S.C. 3729(a)(1)(A) by submitting, or causing to be submitted, false claims to the Medicare and Missouri Medicaid programs for costs associated with spinal surgeries performed by Dr. Fonn. Count III alleges that the Defendants violated 31 U.S.C. 3729(a)(1)(C) by conspiring to violate the FCA as set forth in Counts I and II. The United States contends that the claims were all tainted by the Defendants' illegal kickback scheme, making each claim false. The government also has causes of action in the alternative for Payment under Mistake of Fact and Unjust Enrichment premised on the same factual conduct.

II. Relevant Legal Standards

A. The False Claims Act

The FCA is “the Government’s primary litigative tool for combating fraud.” S. Rep. No. 99-345, 99th Cong., 2d Sess. 2, reprinted in 1986 U.S.C.A.N. 5266. When enacting the False Claims Act, “Congress wrote expansively, meaning ‘to reach all types of fraud, without qualification, that might result in financial loss to the Government.’” *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

An individual is liable under the FCA whenever he or she “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” by the government, or conspires to do so. 31 U.S.C. § 3729(a)(1)(A), (a)(1)(C); *United States v. Advance Tool Co.*, 902 F. Supp. 1011, 1016 (W.D. Mo. 1995), *aff’d without opinion*, 86 F.3d 1159 (8th Cir. 1996). The United States has brought claims against Defendants under both subsections (a)(1)(A) and (a)(1)(C).

1. False Claims Liability: Subsection (a)(1)(A)

To recover under subsection (a)(1)(A) of the FCA, the United States must show:

(1) Defendants submitted or caused to be submitted a claim for payment to the Medicare or Medicaid program; (2) the claim was false or fraudulent; (3) Defendants acted “knowingly,” and; (4) the falsity or fraud was material to the Medicare and Medicaid programs’ payment decisions. *See* 31 U.S.C. § 3729(a)(1)(A); *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001-04 (2016); *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016); *see also* Order Denying Defs.’ Mot. for Summ. J. (#277) at 6.

i. Claims

Proving the first element of FCA liability does not require proof that Defendants personally prepared, signed, or directly submitted each and every claim to the federal government that is at issue in this case.¹ Instead, “[t]he FCA places liability not only on persons who cause false claims to be submitted . . . but also on those who cause the claims . . . to be false in the first place.” *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d 730, 738 (N.D. Ill. 2010) (citing 31 U.S.C. §§ 3729(a)(1), (a)(2)); *United States v. Bornstein*, 423 U.S. 303, 313 (1976); *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 539-43 (1943)); *see also* Order Denying Defs.’ Mot. for Summ. J. (#277) at 7-8. “The wealth of case law supports the proposition that the FCA reaches claims that are rendered false by one party, but submitted to the government by another.” *Mason*, 731 F. Supp. 2d at 738 (citing *Bornstein*, 423 U.S. at 313; *Hess*, 317 U.S. at 539-43); *see also United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 390 (1st Cir. 2011) (“We have made clear that unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party.”).

The Supreme Court has repeatedly confirmed this principle. In *Hess*, the Court held that the language of the FCA “indicate[s] a purpose to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud.” 317 U.S. at 544. In *Bornstein*, a subcontractor was held liable under the FCA for causing a contractor to submit claims seeking payment for materials that the contractor did not realize were labeled

¹ “Medicaid claims submitted to a state are also ‘claims’ to the federal government under the FCA.” *United States v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008). In 2009, Congress clarified the definition of “claim,” consistent with this and other judicial determinations. *See* Fraud Enforcement and Recovery Act of 2009, [Pub.L. 111-21](#), § 4, 123 Stat. 1621 (May 20, 2009), codified at 31 U.S.C. § 3729(b)(2)(A).

incorrectly. 423 U.S. at 309-13. Relying in part on that case, the First Circuit expressly rejected a defendant's argument that the claim submitter must know of the fraud. *Hutcheson*, 647 F.3d at 390. In *Hutcheson*, a case factually similar to this matter, the First Circuit held the defendant device manufacturer could be held liable under the FCA for causing a hospital to submit kickback-tainted claims, notwithstanding the facts that (a) the device manufacturer had not submitted the claims, and (b) there was no allegation that the hospital that did submit the claims was aware of the AKS violation. *Id.* at 388-92; *see also United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004) (emphasizing that defendant's liability "did not turn on the whether the actual presenters were 'duped' or participated in the fraudulent scheme").

ii. Falsity

It is well-established that a claim tainted by a kickback is false for purposes of FCA liability. In 2010, Congress amended the AKS to clarify that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)). This Court recognized as much in its order denying Defendants' motion to dismiss and their motion for summary judgment. *See Order Denying Defs.' Mot. to Dismiss (#98)* at 6-7 ("A claim that violates the AKS, in that it includes items or services that were referred or recommended in exchange, directly or indirectly, for remuneration, is 'false' for the purposes of the FCA."); *Order Denying Defs.' Mot. for Summ. J. (#277)* at 7; *see also United States ex rel. Lutz v. Bluewave Healthcare Consultants, Inc.*, 853 F.3d 131, 135 (4th Cir. 2017) ("[a]n AKS violation that results in a federal health care payment is a per se false claim under the FCA.").

Even before the 2010 amendment, courts—including this Court—had held that “[c]ompliance with the AKS is a condition of reimbursement from Medicare programs, and a violation of the AKS is sufficient to state a claim under the False Claims Act.” *United States ex rel. Health Dimensions Rehab., Inc. v. RehabCare Grp., Inc.*, No. 4:12CV00848 AGF, 2013 WL 4666338, at *4 (E.D. Mo. Aug. 30, 2013) (citing *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 94 (3d Cir. 2009); Order Denying Defs.’ Mot. for Summ. J. (#277) at 7; *United States v. Omnicare, Inc.*, No. 07 C 05777, 2013 WL 3819671, at *9 (N.D. Ill. July 23, 2013); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 266 (D.D.C. 2002) (“*Pogue I*”));² *United States ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (“*Pogue II*”) (“Legion other cases have held violations of AKS and Stark can be pursued under the FCA, since they would influence the Government’s decision of whether to reimburse Medicare claims.”); *see also Hutcherson*, 647 F.3d at 394-95; *United States v. Rogan*, 517 F.3d 449, 452-53 (7th Cir. 2008); *McNutt v. Haleyville Med. Supplier, Inc.*, 423 F.3d 1256, 1259-60 (11th Cir. 2005); *United States ex rel. Thompson v. Columbia HCA Healthcare Corp.*, 125 F.3d 899, 902-03 (5th Cir. 1997). The upshot is that, both before and after the March 2010 amendments to the AKS, a violation of the AKS has been deemed a material falsehood actionable under the FCA. The 2010 amendments merely confirmed Congress’ agreement with the many courts that, in deciding FCA cases predicated upon AKS violations, recognized that a claim filed in violation of the AKS is necessarily false for purposes of the FCA.

² Because the complaint in *RehabCare Group* alleged conduct in beginning in 2006, this Court was applying the pre-2010 version of the AKS. The Court’s decision also cited approvingly opinions that were issued before 2010.

Claims tainted by an AKS violation that are necessarily false can give rise to liability under either an express false certification theory or an implied false certification theory. *See, e.g., Escobar*, 136 S. Ct. at 2001; *see also United States ex rel. Wilkens v. United Health Group, Inc.*, 659 F.3d 295, 306 (3d Cir. 2011) (explaining the two theories); *cf. Hutcheson*, 647 F.3d at 385. Under the former, a defendant can be held liable when it expressly certifies that it is in compliance with the AKS in connection with its claim for payment from Medicare or Medicaid, but has violated the statute. *See, e.g., Rogan*, 450 F. Supp. 2d at 708-09, 724; *see also Thompson*, 126 F.3d at 902. Alternatively, under an implied false certification theory, a defendant violates the FCA when it submits a claim to the government in circumstances that involve misleading half-truths and omissions. *See, e.g., Rogan*, 450 F. Supp. 2d at 717-18, 724; *see also United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 177-78 (4th Cir. 2017); *Wilkins*, 659 F.3d at 313-14.

In *Escobar*, the Supreme Court recently affirmed the implied false certification theory of liability. In that case, although the claims submitted by the defendant were not expressly false on their face, the Supreme Court found that they contained “misleading half-truths.” *Escobar*, 136 S. Ct. at 2001. The Court stated: “When, as here, a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant’s representations misleading with respect to the goods or services provided.” *Id.* at 1999. Furthermore, the standard adopted in *Escobar* is not the exclusive test for implied certification liability. Rather, the Court expressly left open the question whether implied certification liability can exist even in the absence of any representation on the claim form. 136 S. Ct. at 2000 (“We need not resolve whether all claims for payment implicitly represent that the billing party is legally entitled to

payment.”); *see also* *Badr*, 857 F.3d at 178 & n.3. Thus, the Court left intact the rulings by a majority of lower courts that have recognized the viability of implied certification liability under the FCA in multiple scenarios not considered by the Supreme Court in *Escobar*. *See, e.g., Wilkens*, 659 F.3d at 306 (collecting cases adopting an implied certification theory); *see also* *Badr*, 857 F.3d at 178 & n.3; *United States ex rel. Wood v. Allergan, Inc.*, No. 10-CV-5645, 2017 WL 1233991, at *28 (S.D.N.Y. Mar. 31, 2017) (applying the implied certification theory in an AKS case post-*Escobar*); *Rose v. Stephens Inst.*, No. 09-cv-05966-PJH, 2016 WL 5076214, *5 (N.D. Cal. Sept. 20, 2016) (appeal pending before the 9th Circuit) (stating that *Escobar* has not altered the well-established body of implied certification case law).

iii. Knowledge

Under the FCA, “knowingly” means the individual: “(i) has actual knowledge of the information; (ii) “acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. . . .” 31 U.S.C. § 3729(b)(1)(A). Critically, under the FCA, “no proof of specific intent to defraud is required.” 31 U.S.C. § 3729(b)(1)(B); *cf. Minn. Ass’n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002); *United States v. Coop. Grain Supply Co.*, 476 F.2d 47, 55-60 (8th Cir. 1973).

iv. Materiality

A claim is “material” if it has “a natural tendency to influence, or is capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4); *see also* *Escobar*, 136 S. Ct. at 2002. In *Escobar*, the Supreme Court observed that this definition borrows from other federal statutes and descends from the common law, as recognized in earlier Court decisions. *Escobar*, 136 S.Ct. at 2002. (citing *Neder v. United States*, 527 U.S. 1, 16

(1999); *Kungys v. United States*, 485 U.S. 759, 770 (1988)). Courts may analyze materiality from either the perspective of a “reasonable” person or the particular defendant. *Id.* at 2002-03 (“[A] matter is material . . . (1) ‘[if] a reasonable [person] would attach importance to [it] in determining his choice of action in the transaction’; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter ‘in determining his choice of action,’ even though a reasonable person would not.”) (citing Restatement (Second) of Torts § 538 (1977)) (quotation marks omitted). So long as a matter could be or is a “substantial factor” in determining the government’s course of conduct, it is material. *See* 26 R. Lord, *Williston on Contracts* § 69:12 (4th ed. 2003).

In *Escobar*, the Supreme Court identified several factors bearing on the materiality inquiry, including whether the requirement is labeled a condition of payment, 136 S. Ct. at 2003, whether the violation goes to the “essence of the bargain,” *id.* at 2003 n.5 (quoting *Junius Constr. Co. v. Cohen*, 257 N.Y. 393, 400 (1931)), whether the violation is significant or “minor or insubstantial,” *id.* at 2003, and whether the government took action in this or other cases when it had knowledge of similar violations, *id.* at 2003-04. On remand, the First Circuit observed that “The language that the Supreme Court used in [*Escobar*] makes clear that courts are to conduct a holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive.” *United States ex rel. Escobar v. United Health Servs. Inc.*, 842 F.3d 103, 109 (1st Cir. 2016); *see also* *Badr*, 857 F.3d at 178-79.

Since *Escobar*, at least one court has had “no trouble concluding that compliance with the AKS is a ‘material’ condition of payment.” *Woods*, 2017 WL 1233991, at *28; *see also* Order Denying Defs.’ Mot. for Summ. J. (#277) at 8 (rejecting Defendants’ materiality argument). As described below, violation of the AKS may lead to criminal penalties as well as substantial

administrative penalties (including mandatory exclusion from participation in federal healthcare program business), as well as damages and civil penalties under the FCA. In addition to these factors, Congress itself reconfirmed the materiality of AKS compliance by its 2010 amendment making clear that “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g). Thus, under a “holistic” approach, AKS violations are indisputably “material.”

2. Liability under subsection (a)(1)(C)

To establish liability for conspiracy to violate the FCA under 31 U.S.C. § 3729(a)(1)(C), the United States must prove: (1) the existence of an unlawful agreement between Defendants to get a false or fraudulent claim allowed or paid by the government; and (2) at least one act performed in furtherance of that agreement. *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009); *accord United States ex rel. Atkinson v. PA. Shipbuilding Co.*, 473 F.3d 506, 514 (3d Cir. 2007); *cf. United States ex rel. Miller v. Bill Harbert Int’l Const., Inc.*, 608 F.3d 871, 899 (D.C. Cir. 2010).

At least one district court in the Eighth Circuit has posited a third element: “that the United States suffered damages as a result of the false or fraudulent claim.” *United States v. Hawley*, 544 F. Supp. 2d 787, 811 (N.D. Iowa 2008) (citing *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005); *In re Temporomandibular Joint (TMJ) Implants Prods. Liability Litig.*, 113 F.3d 1484, 1498 (8th Cir. 1997)), *rev’d on other grounds*, 619 F.3d 886 (8th Cir. 2010). The district court’s suggestion in *Hawley* is the subject of a split in authority. *Compare Hawley*, 544 F. Supp. 2d at 811 *with Grubbs*, 565 F.3d at 188 (“Notably, stating a claim under § 3729(a)(1) does not require actual or specific damages, as the statute imposes a liquidated civil penalty on violators.”); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 n.7

(4th Cir. 1999) (“In fact, there is no requirement that the government have suffered damages as a result of the fraud.”) (collecting cases); *see also United States ex rel. Barlett v. Tyrone Hospital, Inc.*, 234 F.R.D. 113, 123 (W.D. Pa. 2006) (rejecting the imposition of a damages element: “Clearly, damages are not necessary to make a claim of conspiracy under the FCA, and therefore to recover the civil penalty and costs.”). For an in-depth discussion of this controversy and compelling reasons why the damages element should not apply, *see United States ex rel. Wilkins v. North American Construction Corp.*, 173 F. Supp. 2d 601, 639 n.33 (S.D. Tex. 2001).

The Eighth Circuit, though cited obliquely in *Hawley*, has not opined directly on whether damages are required to be proved under 31 U.S.C. § 3729(a)(1)(C). The government contends that, for the reasons stated in *Wilkins* and other similar opinions that have reached the same conclusion, damages need not be proven in order for it to prevail under subsection (a)(1)(C). *See Wilkins*, 173 F. Supp. 2d at 639 n.33; *see also Grubbs*, 565 F.3d at 188; *Harrison*, 176 F.3d at 785 n.7 (4th Cir. 1999); *Barlett*, 234 F.R.D. at 123.

General civil conspiracy principles apply to FCA conspiracies. *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 n. 3 (7th Cir. 1999). A defendant’s membership in a FCA conspiracy case can be proven by either direct or circumstantial evidence. *United States v. Murphy*, 937 F.2d 1032, 1039 (6th Cir. 1991) (no express conspiracy agreement is necessary for proof purposes). Because of the “secretive character” of FCA conspiracies, direct evidence is often “elusive,” meaning a defendant’s participation is often established by circumstantial evidence. *Rogan*, 495 F. Supp. 2d at 718 (noting even a single act or conversation can suffice to connect a defendant to a conspiracy); *see also Halberstam v. Welch*, 705 F.2d 472, 486 (D.C. Cir. 1983); *Firststar Bank Sioux City, N.A. v. Beemer Enters., Inc.*, 976 F. Supp. 1233, 1240-41 (N.D. Iowa 1997) (Court finding circumstantial evidence of civil conspiracy was enough to

create genuine issues of material fact after reviewing entire record, even when defendant claimed allegations were implausible). “The Court may consider the conduct, knowledge, and statements of the defendant in establishing his participation in a conspiracy” and even “[a] single act or conversation can ‘suffice to connect the defendant to the conspiracy if that act leads to the reasonable inference of intent to participate in an unlawful enterprise.’” *Rogan*, 459 F. Supp. 2d at 719. Circumstantial evidence, especially evidence of concerted activity by the conspirators directed toward achievement of a common goal, is just as probative as direct evidence. *See generally United States v. Jackson*, 204 F.3d 812, 814 (8th Cir. 2000); *United States v. Michaels*, 726 F.2d 1307, 1311 (8th Cir. 1984). Additionally, FCA co-conspirator statements are admissible if a foundation is laid under Fed. R. Evid. 801(d)(2)(E). *Rogan*, 459 F. Supp. 2d at 719.

B. The Federal Anti-Kickback Statute

The AKS provides that:

whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or,

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony.

42 U.S.C. § 1320a–7b(b)(1).

1. Remuneration

Remuneration is broadly construed, and is intended to include “anything of value.” *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006); accord *United States v. Bay State Ambulance & Hosp.*, 874 F.2d 20, 29-31 (1st Cir. 1989) (finding that “Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.”); see also Order Denying Defs.’ Mot. for Summ. J. (#277) at 8. “Congress’s intent in placing the term ‘remuneration’ in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever.” *United States v. Shaw*, 106 F. Supp. 2d 103, 114 (D. Mass. 2000) (citing 42 C.F.R. Part 1001, 56 Fed. Reg. 35952-01 (July 29, 1991)); see also *United States ex rel. Fry v. The Health All. of Greater Cincinnati*, No. 1:03-CV-00167, 2008 WL 5282139, at *7 (S.D. Ohio Dec. 18, 2008) (agreeing that “remuneration” includes “anything of value in any form whatsoever.”). One court has decided, for example, that a defendant’s practice of providing reduced-price housing only to individuals who participated in its drug-treatment program was “a form of remuneration: it is an in-kind benefit provided at below market value to Medicaid beneficiaries.” *United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 751, 756 (S.D.N.Y. 2015). Another court concluded that the defendant’s obligation to construct and renovate office space for future occupation by referring physician tenants, especially at a below fair market value rental rate, was a financial benefit to those physicians. *United States ex rel. Bingham v. HCA, Inc.*, No. 13-cv-23671-MGC, 2016 WL 344887, at *6 (S.D. Fla. Jan. 28, 2016).

Under the AKS, the Government does not have to show that any payments involved in the scheme lacked fair market value. *Bay State Ambulance & Hosp.*, 874 F.2d at 29-30 (“The trial court did not err in not specifically instructing the jury that the government had to prove that

the payments received were not reasonable for the actual work done. The gravamen of Medicare Fraud is inducement.”); *United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) (“Because at least part of the payments to Borrasi was intended to induce [the recipient] to refer patients to [the payor], the statute was violated, even if the payments were also intended to compensate for professional services.”) (quotation marks omitted). “Once the United States has demonstrated proof of each element of the [AKS] . . . the burden shifts to the defendant to establish that his conduct was protected by a safe harbor or exception.” *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008).

Moreover, Defendants can violate the AKS even if they do not directly receive remuneration. *See United States ex rel. Nehls v. Omnicare, Inc.*, 2013 WL 3819671 (N.D. Ill. July 23, 2013). *Nehls* involved FCA claims arising from an AKS violation, and the remuneration at issue involved payments to the defendant’s son. Rejecting the defendant’s argument that his conduct was not within the scope of the AKS because those payments were not made directly to him, the court held:

It is probably true that in the classic AKS case, an economic benefit of some sort inures to the referral source, whether that benefit comes in the form of cash, a discount, or even the opportunity to earn revenue. But direct economic benefit does not delimit the scope of unlawful remuneration under the statute. Here, the economic benefit inured to the benefit of a member of Morris’s immediate family . . . and that is sufficient evidence for a jury to reasonably conclude that Morris indirectly benefitted as well

Id. at 13 (citations omitted).

2. Inducement

The AKS is violated if “one purpose” of the remuneration was to induce or reward federal healthcare program referrals. *See, e.g., Borrasi*, 639 F.3d at 780-82; *United States v. McClatchy*, 217 F.3d 823, 835 (10th Cir. 2000); *United States v. Davis*, 132 F.3d 1092, 1094 (5th

Cir. 1998); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985); *see also* Order Denying Defs.’ Mot. for Summ. J. (#277) at 9. As the Court noted in *Greber*, when Congress amended the Act in 1977 to deter “the growing problem of fraud and abuse in the system,” it added a proscription against the payment of “remuneration,” which contemplates the rendering of a service, whereas the predecessor statute merely prohibited payment of “kickbacks,” for which no service is rendered. *Greber*, 760 F.2d at 71-72. The *Greber* court thus concluded that the “one purpose” test is consistent with the legislative intent behind the amended Act. *Id.* at 69, 72. The government, therefore, need not show that inducing referrals was the “primary purpose” of the remuneration.

C. Standard of Proof in an FCA/AKS Case

The United States’ burden of proof in establishing an AKS violation is the familiar civil preponderance of the evidence standard and not the heightened criminal standard that Defendants have repeatedly urged. The Court has correctly held the preponderance standard to be the appropriate standard, *see* Order (#87) at 2, and there is no reason to reconsider or amend that ruling now.

The FCA contains a very clear and concise statement concerning the standard of proof in cases brought under the FCA.

In any action brought under section 3730, the United States shall be required to prove *all essential elements* of the cause of action, including damages, *by a preponderance of the evidence*.

31 U.S.C. § 3731(d) (emphasis added). This section was added as part of the 1986 amendments to the FCA. The purpose of the 1986 amendments was to ensure the FCA could achieve its intended purpose – “to reach all types of fraud, without qualification, that may result in financial loss to the Government.” S. Rep. 99-345, at 19 (“strongly endorses[ing]” this articulation of the

FCA's purpose from *Neifert-White*, 390 U.S. 228). To achieve this goal, among other things, Congress specifically sought to clarify some perceived confusion about the FCA standard of proof. The Senate Report explaining the FCA's 1986 amendments states:

Section 3 of the bill amends section 3731 by adding a new subsection (c) [now subsection (d)] to make clear that in civil fraud actions, the Government is required to prove all essential elements of the cause of action by a preponderance of the evidence. Traditionally, the burden of proof in a civil action is by a preponderance of the evidence. However, this point is not expressly addressed in the current act, and the case law is fragmented and inconsistent. Inasmuch as False Claims Act proceedings are civil and remedial in nature and are brought to recover compensatory damages, the Committee believes that the appropriate burden of proof devolving upon the United States in a civil False Claims Act suit is by a preponderance of the evidence.

S. Rep. No. 99-345, 30-31, 1986 U.S.C.C.A.N. 5266, 5295-96.

Even before the 1986 amendments, the Eighth Circuit found that the appropriate burden of proof for violations of the FCA was preponderance of the evidence. *See Federal Crop Ins. Corp. v. Hester*, 765 F.2d 723, 727-28 (8th Cir. 1985) ("we think the preponderance of the evidence standard is appropriate under the [FCA].") In enacting the 1986 amendments, Congress specifically cited *Hester* as stating the appropriate burden for proving violations of the FCA. S. Rep. No. 99-345 at 31, 1986 U.S.C.C.A.N. at 5296.

Every court to actually decide the issue of the appropriate burden for establishing an FCA claim predicated on a violation of the AKS has held that the correct burden of proof is preponderance of the evidence. *Health Dimensions Rehab.*, 2013 WL 5340910, at *4; *United States v. Campbell*, 2011 WL 43013, at *5 (D.N.J. Jan. 4, 2011); *Rogan*, 459 F. Supp. 2d at 716, n. 12; *see also Sedima, S.P.R.L. v. Imrex Co., Inc.*, 473 U.S. 479, 491 (1985).

D. Causation

As discussed above, the AKS was amended in 2010 to re-enforce that "a claim that

includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of” the FCA. 42 U.S.C. § 1320a-7b(g) (emphasis added). In the past, Defendants have contended that the phrase “resulting from” requires a showing that “but for” the alleged kickbacks, Dr. Fonn would have done different procedures or done them in a different manner or utilized different devices. Defs.’ Memo in Support of Mot. for Summary Judgment (#199) at 41, 47-48; *see also* Defs.’ Reply in Support of Their Motion to Dismiss (#84). Defendants contend that the AKS amendment’s use of the phrase “resulting from” now injects a new – and more stringent – “but for” causation requirement into the standard of falsity under the FCA and requires the government to formally plead and prove that all items or services provided under an illegal kickback relationship would not have been referred without the bribes or kickbacks inducing the doctor’s referral. This argument reflects a fundamental misunderstanding of purpose underlying the 2010 AKS amendment which this and other Courts have properly and repeatedly rejected. Order Denying Defs.’ Mot. for Summ. J. (#277) at 9; Order Denying Defs.’ Mot. to Dimiss (#97).

The Affordable Care Act’s (ACA) legislative history clearly establishes that the 2010 amendment to the AKS was intended to clarify “that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves.” 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (Sen. Kaufman). In *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323 (S.D.N.Y. 2014), the court rejected the “but for” argument after reviewing the legislative history behind the 2010 AKS amendment, finding it merely clarified well-established law and that any claims submitted under an illegal kickback relationship are false for FCA purposes. *See also United States ex rel. Wood v. Allergan, Inc.*,

No. 10-CV-5645 (JMF), 2017 WL 1233991, at *25 (S.D.N.Y. Mar. 31, 2017) (holding that the ACA “makes plain” that claims submitted in violation of AKS after the ACA’s effective date are “legally sufficient” to state plausible FCA claim). These and other cases correctly interpret the scope and meaning of the 2010 AKS amendment. Violations of the AKS are *per se* false under the FCA as a matter of law and the government need not prove “but for” causation.

E. Common Law Claims

In the alternative to its causes of action under the FCA, the government has brought causes of action in this matter for unjust enrichment and payment under mistake of fact. In the Eighth Circuit, an unjust enrichment claim is a matter of federal common law. *United States v. Applied Pharmacy Consultants, Inc.*, 182 F.3d 603, 606-09 (8th Cir. 1999) (affirming judgment for United States against Medicare provider who submitted inflated claims for medical devices under unjust enrichment theory); *see also United States ex rel. Roberts v. Aging Care Home Health, Inc.*, 474 F. Supp. 2d 810, 820 (W.D. La. 2007) (granting summary judgment for United States under unjust enrichment theory where statute barred defendant from receiving any Medicare payments in the first place); *Visiting Nurse Ass’n v. Thompson*, 378 F. Supp. 2d 75, 99 (E.D.N.Y. 2004) (granting government summary judgment in FCA/unjust enrichment case where alternative causes of action were based on same factual predicates). The elements of an unjust enrichment claim under federal common law are: “(1) the Government had a reasonable expectation of payment, (2) [the defendant] should reasonably have expected to pay, or (3) ‘society’s reasonable expectations of person and property would be defeated by nonpayment.’” *Rogan*, 459 F. Supp. 2d at 728 (quoting *Provident Life & Accident Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990)). For an unjust enrichment claim, the intent of the party receiving the funds is irrelevant, and proof of fraud or wrongful conduct by the defendant is not required.

Am. Cleaners & Laundry Co., Inc. v. Textile Processors, 482 F. Supp. 2d 1103, 1118 (E.D. Mo. 2007); *United States v. Davis*, 666 F. Supp. 641, 644 (S.D.N.Y. 1987).

The government's payment by mistake theory is premised upon the principle, long recognized by the Supreme Court and the lower courts, that "[t]he Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid. 'No statute is necessary to authorize the United States to sue in such a case. The right to sue is independent of statute. . . .'" *United States v. Wurts*, 303 U.S. 414, 415-16 (1938) (footnote omitted) (quoting *United States v. Bank of the Metropolis*, 15 Pet. 377, 401 (1841)). Further, "the Government's right to recover funds, from a person who received them by mistake and without right, is not barred unless Congress has 'clearly manifested its intention' to raise a statutory barrier." *Wurts*, 303 U.S. at 416 (citation omitted); *see also Stone v. United States*, 286 F.2d 56, 58-59 (8th Cir. 1961) ("Where monies are erroneously paid by agents of the United States, whether the error be one of fact or of law, the Government may always recover the money improperly paid."). The obligation to refund to the Treasury money paid in error or without legal authorization will not be excused, even if the party who erroneously received it acted in "good faith" and could suffer "hardship" if required to return the funds. *See, e.g., Weiss v. United States*, 296 F.2d 648, 649-50 (5th Cir. 1961) (collecting cases).

III. Specific Evidentiary Issues

A. Summary Charts

At trial, the government may offer summaries or charts which will be used to prove the contents of the voluminous records supporting its claims. Fed. R. Evid. 1006. Such charts are admissible as convenient compilations of the underlying evidence upon which they are based. *United States v. Possick*, 849 F.2d 332, 339 (8th Cir. 1988). Charts are often used in health care

fraud cases because the underlying evidence can be complex and paper-intensive. *See, e.g., United States v. Campbell*, 845 F.2d 1374, 1381 (6th Cir. 1988) (chart admissible where it saved jury from reviewing hundreds of pages of technical information in Medicare fraud case); *United States v. Gold*, 743 F.2d 800, 816 (8th Cir. 1984) (no abuse of discretion to admit chart summarizing evidence in Medicare fraud case). Charts and summaries admitted under Rule 1006 may be sent to the jury at the trial court's discretion, with whatever limiting instructions the trial court determines to be appropriate. *Possick*, 849 F.2d at 339. The underlying evidence upon which the government's charts are based (*e.g.*, monthly bank statements, spinal implant invoices, and other business records) was disclosed to Defendants during discovery, and any charts will be disclosed to the defense before trial as exhibits.

B. Self-Authenticating Business Records

The United States may also seek to introduce various business records under Federal Rules of Evidence 803(6) and 902(11). The business records exception to the hearsay rule is well established.

Under Rule 902(11), business records are self-authenticating and can be introduced at trial without a live witness if they are accompanied by an affidavit completed by the custodian or other qualified person establishing that the records meet the requirements of Rule 803(6). *United States v. Klinzing*, 315 F.3d 803, 809 (7th Cir. 2003) (business records admissible without foundational testimony from the record custodian so long as the records are authenticated by declaration); *see also United States v. Laguerre*, 119 Fed. App'x 458, 460-61 (4th Cir. 2005). If the declaration meets the necessary foundational requirements and the offering party provides timely notice, then the business records are admissible without live records custodian testimony. *Klinzing*, 315 F.3d at 809. Rule 803(6) was specifically amended to avoid the expense and

inconvenience of producing time-consuming foundation witness testimony in situations where the authenticity of the business records could be confirmed by written declarations. *Id.*

Business records custodian affidavits frequently cover a collection of records. *Sheppard v. Liberty Mut. Ins. Co.*, No. 16-2401, 2017 WL 480601, at *4 (E.D. La. Feb. 2, 2017) (Rule 901 “merely requires some evidence which is sufficient to support a finding that the evidence in question is what its proponent claims it to be.”).

Here, the government provided notice of its intent to use these business records certifications before trial. Each of the certificates provided to Defendants is signed by a records custodian or some other qualified individual, and recites all of the foundational requirements for business records. It would be resource-intensive and unnecessary to require live witness testimony regarding the authenticity of these business records offered as evidence.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 25, 2017, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the following:

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